February 14, 2007

Dear Honorable Members of the House Judiciary Committee:

Legislation pending before the Michigan House to repeal the limits on product liability suits involving FDA-approved drugs is both bad law and bad policy.

Current Michigan law provides that a prescription drug approved by the FDA is "not defective," and, with certain important exceptions, the manufacturer is "not liable" for any injuries. The proposed legislation would repeal this law, *retroactively to 1996*. Thus, products that were not defective when they were manufactured, sold, or used, and that are not defective today, could suddenly be deemed to have been defective for the last 11 years. Companies could be held liable and forced to pay damages for actions that were not subject to liability at the time they were undertaken.

This Legislature would not enact a bill imposing fines on anyone who paid $4.75 an hour in 1996, even though that was the lawful minimum wage at that time. Nor would the Legislature even consider passing a law today declaring retroactively that it was illegal to have driven a car in 1996 that got less than 20 miles per gallon of gasoline. Fundamental fairness, embodied in the Due Process Clause of the U.S. and Michigan Constitutions, bars the Legislature from retroactively making previously legal conduct, illegal. Yet that is precisely what the proposed legislation would do. It is therefore unconstitutional.

Even if this legislation could withstand constitutional challenge, and even if it were not retroactive, it would still be bad policy. The current Michigan law reflects the Legislature's judgment that that product liability litigation can impede development of new life-saving medicines, raise the cost of drugs to consumers, and interfere with the FDA's regulation of drug safety. The FDA itself has agreed that product liability suits involving FDA-approved drugs can undermine public health. In January 2006, the FDA made clear that its regulation of the safety, effectiveness and labeling of prescription drugs was already painstaking and comprehensive. Additional disclosure requirements imposed through litigation, the Agency warned, thus "are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug." The FDA also worried that state tort suits challenging FDA-approved labels could "encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of FDA—sometimes on behalf of a single individual or group of individuals." That result, the FDA stated, also could harm public health.

When the Agency responsible for regulating the safety of drugs and ensuring the health of each and every one of us states firmly that product liability suits do not help, but rather hinder its mission -- when, in other words, the FDA says that Michigan got it right -- it would be ill-advised for this Legislature to reverse course and get it wrong. As this Legislature has recognized repeatedly, generating more lawsuits is almost never the best answer.

Pfizer therefore urges that the proposed legislation be defeated.

Sincerely,

Sandra Phillips
Pfizer Senior Vice President and Associate General Counsel